

REMARKS

In response to the Office Action mailed March 11, 2008, Applicants respectfully request reconsideration. Claims 45 and 47-84 were previously pending in this application. Claims 85 & 86 were previously withdrawn. Please cancel all previously pending and withdrawn claims 45 & 47-86. The current claims 87-117 have been added.

Each stage of a two stage process was separately described in the previous claims 45 and 53. Those two stages, in general, have been consolidated into a single process described by each of the newly added claims 87-117. Support for the newly added claims can be found in the previously pending claims 45 and 47-84. No new matter has been added.

Claim Rejections – 35 USC § 103

The previous claims 45 and 47-84 were rejected under 35 USC 103(a) as being unpatentable over Nyborg et al. (US 5,677,472) in view of Fischer et al. (US 5,840,661), Unger et al. (US 5,585,112), and Unger (US 6,416,740), and as evidenced by Senior (Biochemica et Biophysica Acta 1991, 1062, pp. 77-82).

Applicant asserts that none of these citations above and no combination of any of these citations teach or suggest all of the limitations of the presently amended claims. Therefore, the cited prior art fails to render obvious the currently claimed invention.

The currently amended claims:

The currently amended claims now consolidate the dissolution-precipitation process for making a *lipid blend* with the subsequent process for making a *lipid suspension*. The resulting combination comprises the following steps:

- (a) contacting at least two lipids with a first non-aqueous solvent, whereby dissolution of the lipid blend is achieved. [This permits starting from purified materials for production of pharmaceutical grade materials.]
- (b) contacting the resulting solution with a second non-aqueous solvent. [This solvent is selected to cause the lipids to precipitate into a solid lipid blend.]

(c) collecting the resulting solid lipid blend. [Steps (b) and (c) allow the use of a purified solid, blended material in the later steps of the process. The blended material has processing advantages versus working with unblended material.]

(d) contacting the blended lipid solids with a third non-aqueous solvent to dissolve the lipid blend. [This permits the already blended solids to be dissolved, but this time in a metered fashion as a blended material. The third solvent also is selected to be miscible with the aqueous solvent in step (e).]

(e) contacting the lipid blend solution with an aqueous solution to yield a lipid suspension. [This allows better formation of the lipid particles in the suspension, than if the lipid blend were put directly into the aqueous solvent.]

It is believed that the rejections held against the previous claim set no longer apply to the currently amended claims because the combination of the cited prior art fails to teach the limitations of steps (a-e).

The prior art:

According to the examiner, “Nyborg et al. specifically indicate separation of phospholipids into different phases.” In doing so, Nyborg’s method of partially *separating* the lipid components from buttermilk has little in common with the currently claimed method of *combining* lipids to form a suspension. Steps (a-c) of the current invention describe the deliberate combination of separate phospholipids into a single blended solution followed by the quantitative precipitation of the relatively pure lipid blend as a single solid phase. Nyborg’s separation protocol starts with a mixture, not separate phospholipids, and disburses the lipids into three phases - “precipitate,” brown phase,” and “solution” - all of which comprise impure mixtures of phospholipids. Not only does Nyborg fail to anticipate steps (a-c), but it teaches away from them. Nyborg’s extraction of lipids into organic solvent and the subsequent dilution with a second organic solvent teaches one of skill in the art how to obtain a partial precipitation of impure lipids in diminished quantities. This is hardly the result steps (a-c), which yield an efficient precipitation of highly pure lipids into a quantitatively controlled blend of such lipids. Nyborg further does not teach or suggest the combination of steps (d) and (e).

The Examiner states that Nyborg does not teach methyl t-butyl ether, but that the teachings of Fischer et al. show that methyl t-butyl ether and acetone are equivalent solvents.

Respectfully, the applicant points out that Fischer's teaching of a single instance in which acetone and methyl t-butyl ether were both adequate for some purpose is not a teaching or suggestion that they are "equivalent" for all other purposes. There is reason to substitute the methyl t-butyl ether of Fischer for the acetone of Nyborg. However, even assuming that methyl t-butyl ether could be substituted by acetone in the Nyborg method, such a substitution fails to teach most of the limitations of the newly amended claims.

The Examiner indicates that two patents, Unger et al. (US 5,585,112) and Unger et al. (US 6,416,740), respectively teach suitable mixtures of phospholipids in combination with perflourobutane and a method for sterilizing phospholipid suspensions. The Examiner adds that Senior et al. couples dipalmitoylphosphatidylethanolamine (DPPE) with methoxypolyethylene glycol (MPEG 5000), and that poly(ethylene glycol) (PEG) and MPEG 5000 are known in the art as equivalent substances to alter the surface area of liposomes. Respectfully, the applicant does not agree with all of the Examiner's assertions regarding the prior art teachings. However, even if the applicant did concede all of these assertions, Fischer, Unger, Unger, and Senior, as described by the Examiner, do not supply those elements of new claim 87 (and the dependent claims) missing from Nyborg. Therefore, the applicant asserts that the presently claimed invention is nonobvious in view of the prior art.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. N0469.70022US02.

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Respectfully submitted,

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